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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,719

11/17/2003

Janel E. Young

ETH5095

2358

25570

7590

10/06/2010

ROBERT'S MLOTKOWSKI SAFRAN & COLE, P.C.

Intellectual Property Department

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1613

NOTIFICATION DATE

DELIVERY MODE

10/06/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/714,719

Applicant(s)

YOUNG ET AL.

Examiner

BLESSING M. FUBARA

Art Unit

1613

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks filed 3/29/2010. Claims 1 and 13 are amended. Claims 1-13 are pending.
- 2.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/2010 has been entered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi et al. ("The prevention of Postoperative Intraperitoneal adhesions by Tranilast: N-(3',4'-dimethoxycinnamoyl) Anthranilic Acid) in Jpn. J. of Surg., (1999), 29, 51-54) in view of Sheffield et al. (US 4,937,254).

7. Adachi describes how to prevent postoperative intraperitoneal adhesions by oral administration of composition comprising tranilast and carboxymethylcellulose prior to and after surgery (see the whole document with emphasis on the abstract and page 52). The carboxymethylcellulose meets the limitation of delivery vehicle of claim 1. Therapeutically effective amount as recited in claim 1 is any amount deemed effective by the artisan.

Administration of 60 mg/kg per day represents a single dose as recited in claim 8 and also meets the limitation of claim 11. The carboxymethyl cellulose is a sustained release excipient so that the composition administered is in sustained release form meeting claims 9 and 10. The oral administration of tranilast composition prior to surgery meets the limitations of systemic administration and thus meets claims 12 and 13. The melted tranilast and the carboxymethylcellulose are in solution so that the carrier composition in claim 3 is met.

8. Adachi does not teach that the composition comprising tranilast is locally administered to tissue at surgical sites to treat adhesions. But, local and/or topical administration of therapeutic agents at surgical sites to treat or inhibit adhesion formation is known for various agents. For example:

9. Sheffield discloses method of inhibiting the formation of post surgical adhesion by administration of compositions to the site of surgical trauma to inhibit the post surgical adhesion (abstract; column 2, lines 34-38; column 3, lines 15-28, 39-56). The composition locally or topically administered at the surgical site comprises non-steroidal anti-inflammatory drug (NSAID) and pharmaceutically acceptable carrier (column 4, lines 12-29); when the composition is carried in a liposome or when the NSAID is encapsulated in a microcapsule, the composition of Sheffield meets the requirements of claim 3; when the polymeric carrier is lactide, the composition of Sheffield meets the requirements of claim 4. Furthermore, Sheffield teaches that the composition can be applied by catheterization using implanted osmotic pump (column 3, lines 29-38) so that when the delivery method is by osmotic pump, the requirement of claim 3 is met.

10. Claim 1 has been amended to say that the direct administration “onto said tissue surfaces at the surgical site for periods of time effective to reduce the area percentage of adhesions formed thereon, relative to systemic administration of Tranilast alone.” “For periods of time effective to reduce the area percentage of adhesions formed thereon” is any time that the artisan deems effective to bring above the reduction in area of adhesion after the topical application upon observation. Claim 13 has similar amendment and the artisan deems effective to bring above the reduction in area of adhesion after the topical application upon observation. The language that the composition that is applied comprises is an open language and does not limit such a composition to Tranilast alone.

11. Therefore, taking the teachings of Adachi and Sheffield, one having ordinary skill in the art at the time the invention was made would have reasonably expectation of success that topical

or oral administration anti-adhesion composition of Adachi or Sheffield or the combined composition of Adachi and Sheffield would produce the expected inhibition of post surgical adhesion.

12. When the composition of Adachi and Sheffield are combined, the composition having tranilast and anti-inflammatory agent meets claims 2, 5 and 6 with the topical administration meeting requirements of claim 2. With regards to claim 7, the basic structure of the analogs is related to the core structure of the tranilast so that it flows that the activities of the analogs and the tranilast would be the same.

13. The amendment to claim 1 requires the delivery vehicle to contain tranilast. The solution of Adachi contains carboxymethylcellulose and tranilast meeting the requirement of amended claim 1. The suitability of the delivery vehicle for use in the local and non-systemic administration in claim 2 is the property of the delivery vehicle.

Response to Arguments

14. Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

15. Applicant argues that the amendment to the claims overcomes the rejection.

16. Response: The amendment to the claims does not overcome the rejection of the claims 1-13 over Adachi in view of Sheffield because "For periods of time effective to reduce the area percentage of adhesions formed thereon" is any time that the artisan deems effective to bring above the reduction in area of adhesion after the topical application upon observation. Claim 13 has similar amendment and the artisan deems effective to bring above the reduction in area of adhesion after the topical application upon observation.

17.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **BLESSING M. FUBARA** whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613